UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 9, 2019

APTEVO THERAPEUTICS INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-37746**	**81-1567056**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2401 4th Avenue, Suite 1050 **Seattle, Washington**	**98121**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (206) 838-0500

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	APVO	The Nasdaq Stock Market LLC

Item. 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Aptevo Therapeutics Inc. (the "***Company***") issued a press release announcing its financial results for the quarter ended March 31, 2019. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission (the "***SEC***") made by the Company, whether made before, on or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 9, 2019.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

APTEVO THERAPEUTICS INC.

Date: May 9, 2019

By: /s/ Marvin L. White
Marvin L. White
President and Chief Executive Officer

For Immediate Release

APTEVO THERAPEUTICS REPORTS FIRST QUARTER 2019 FINANCIAL RESULTS

Achieves 73% Increase in First Quarter 2019 Year-Over-Year IXINITY® Net Revenue

On Target for Launch of New 3,000 IU IXINITY Assay Mid-2019

Advances Enrollment in APVO436 and APVO210 Phase 1 Clinical Studies; Anticipates Top-Line Preliminary Data Read-outs in the Third and Fourth Quarters of 2019

SEATTLE, WA – May 9, 2019 -- Aptevo Therapeutics Inc. (Nasdaq: APVO), a biotechnology company focused on developing novel oncology, autoimmune and hematology therapeutics, today provided a business review and reported its financial results for the first quarter ended March 31, 2019.

"As we reported in our interim business update in April, momentum in both our pipeline and IXINITY programs continues to strengthen in 2019 and we remain on track to achieve several key priorities we outlined for Aptevo this year. These include, advancing our novel, next-generation ADAPTIR candidates through preliminary top-line clinical data read-outs, driving continued adoption of IXINITY through the launch of new growth initiatives, and achieving a 33% reduction in our 2019 cash burn rate," said Marvin L. White, President and Chief Executive Officer.

"We continue to be pleased with the revenue performance for IXINITY, with year-over-year net revenue for IXINITY in the first quarter increasing approximately 73% to $7.0 million compared to $4.1 million in the first quarter of 2018. We anticipate that new growth initiatives that are being implemented beginning this year, including the launch of a larger assay size for IXINITY and pursuit of a pediatric label expansion and ex-US distribution and partnership opportunities, will continue to drive growth of IXINITY through 2019 and beyond."

"Turning to our ADAPTIR™ bispecific pipeline, enrollment in both of the Phase 1 clinical studies of APVO436 (Acute Myeloid Leukemia) and APVO210 (autoimmune diseases) is proceeding on target, with dosing for Cohort 3 in the APVO210 study now underway, and dosing in Cohort 3 anticipated to begin shortly for APVO436. 2019 will be an important year for our next-generation ADAPTIR platform as we anticipate reporting preliminary data read-outs for both ongoing clinical programs this year. Specifically, we anticipate reporting a preliminary read-out on anti-drug antibody (ADA) data for APVO436 in the third quarter and preliminary safety data for APVO436 in the fourth quarter. We look forward to sharing these data with investors to confirm the absence of ADA in our next-generation candidates, as industry-leading T-cell immunogenicity assays show low risk for ADA in our next generation platform."

"For APVO210, we anticipate reporting initial results of the single dose cohorts in the third quarter and reporting preliminary safety data in the fourth quarter. We are also on track to file a clinical trial authorization (CTA) for ALG.APV-527 in the fourth quarter and anticipate beginning Phase 1 clinical development in 2020. We're very encouraged by the progress in our ADAPTIR clinical programs as the first clinical data from our next generation candidates becomes available later this year. As we've previously announced, in preclinical studies, APVO436 showed important differentiation from a competitor bispecific molecule, demonstrating comparable T-cell activation and tumor killing but with less cytokine activation, which could have important advantages with respect to dosing and the therapeutic index for this molecule. We look forward to evaluating these attributes in our ongoing APVO436 clinical program and determining the safety and tolerability profile of APVO210, as a potential first-in-class novel autoimmune therapy," concluded Mr. White.

First Quarter 2019 Highlights

- Achieved 73% increase in year-over-year IXINITY net revenue in the first quarter of 2019 through continued expansion of the patient base for IXINITY
- Progressed plans to launch a new 3,000 IU assay for IXINITY; received approval from the U.S. Food and Drug Administration (FDA) for a Prior Approval Supplement (PAS) describing plans for the manufacture of the new 3,000 IU assay; on track to launch new 3,000 IU assay in mid-2019
- Commenced a Phase 1 clinical study of APVO210 designed to evaluate single and multiple ascending doses in healthy volunteers; dosing in Cohort 3 currently underway; anticipate reporting initial results of the single dose cohorts in the third quarter and reporting preliminary safety data in the fourth quarter of 2019
- Continued enrollment in a dose escalation Phase 1/1b open-label clinical study of APVO436 in patients with Acute Myeloid Leukemia (AML) and High-Grade Myelodysplastic Syndrome (MDS); dosing in Cohort 3 anticipated to commence shortly; anticipate reporting preliminary ADA read-out in the third quarter and reporting preliminary Phase 1 safety data in the fourth quarter of 2019
- Presented new preclinical data for APVO436 at the American Association for Cancer Research (AACR) 2019 annual meeting demonstrating T cell differentiation into effector cells with exposure to APVO436 in preclinical studies, in addition to key data demonstrating potent T-cell cytotoxicity of tumors expressing CD123 with reduced cytokine release, suggesting the potential for increased clinical benefit and an improved safety profile
- Presented new preclinical data for ALG.APV-527 at AACR showing that it was well tolerated in a dose-range finding pilot toxicology study demonstrating no major changes in liver enzyme levels, cytokine levels or immune cell populations, and had an extended half-life of 5-7 days
- Implemented a 33% reduction in Aptevo's 2019 annual cash burn rate; anticipate 2019 cash burn of between $36-$40 million compared to $55-60 million in 2018
- Completed a public equity offering in March 2019 raising gross proceeds of approximately $22 million for Aptevo, strengthening the company's balance sheet and providing additional cash runway beyond validating clinical milestones in the APVO436

and APVO210 Phase 1 clinical development programs anticipated in the third and fourth quarters of 2019, respectively

First Quarter 2019 Financial Results

Cash Position: Aptevo had cash, cash equivalents, and marketable securities as of March 31, 2019 totaling $44.5 million, including $7.5 million in restricted cash.

IXINITY Revenue: Product sales of IXINITY increased by $3.0 million, or 73%, to $7.0 million for the three months ended March 31, 2019, compared to $4.1 million for the same period in 2018. The increase in IXINITY sales in the quarter was primarily related to the continuing expansion of the Hemophilia B patient base for IXINITY and a price increase which went into effect on January 1, 2019.

Cost of Product Sales: Cost of product sales for the three months ended March 31, 2019 increased by $2.1 million, or 116% to $3.8 million compared to $1.8 million for the three months ended March 31, 2018. The increase in cost of product sales is primarily due to the increase in sales in the current quarter as well as the first quarter of 2018 having reduced cost of goods sold due to lower cost inventory that was sold during that quarter.

Research and Development Expenses: Research and development expenses decreased by $0.9 million, to $7.3 million for the three months ended March 31, 2019, compared to $8.2 million for the corresponding period in 2018. The decrease was primarily attributable to a decrease in expenses related to the APVO436 and APVO210 clinical programs, primarily due to the timing of certain manufacturing and clinical trial activities, offset by an increase in expenses related to Aptevo's preclinical programs and general research and development efforts, and an increase in R&D expense for IXINITY related to start-up costs associated with the pediatric clinical study expected to commence in 2019.

Selling, General and Administrative Expenses: Selling, general and administrative expenses decreased by $0.3 million, or approximately 3%, to $7.3 million for the three months ended March 31, 2019, compared to $7.6 million for the same period in 2017. The decrease in SG&A expenses in the first quarter of 2019 was primarily due to reduced personnel and professional services costs.

Net Loss: Aptevo's net loss for the three months ended March 31, 2019 was $(12.0) million or ($0.44) per share, compared to $(13.9) million or ($0.63) per share for the three months ended March 31, 2018.

Financial Statements Follow

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts, unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,011	$ 30,635
Accounts receivable	5,801	5,220
Inventories	4,346	1,785
Prepaid expenses	6,923	6,907
Other current assets	3,561	4,142
Total current assets	57,642	48,689
Restricted cash	7,448	7,448
Property and equipment, net	4,978	5,202
Intangible assets, net	5,043	5,250
Operating lease right-of-use asset	4,481	—
Other assets	1,249	905
Total assets	$ 80,841	$ 67,494
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,043	$ 11,671
Accrued compensation	5,042	3,898
Sales rebates and discounts payable	857	1,245
Other short-term liabilities	1,348	796
Total current liabilities	18,290	17,610
Long-term debt, net	19,415	19,278
Operating lease liability, net of current portion	3,995	—
Other liabilities	11	200
Total liabilities	41,711	37,088
Stockholders' equity:		
Preferred stock: $0.001 par value; 15,000,000 shares authorized, zero shares issued or outstanding	—	—
Common stock: $0.001 par value; 500,000,000 shares authorized; 45,090,219 and 22,808,416 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	45	23
Additional paid-in capital	178,511	157,791
Accumulated deficit	(139,426)	(127,408)
Total stockholders' equity	39,130	30,406
Total liabilities and stockholders' equity	$ 80,841	$ 67,494

Aptevo Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts, unaudited)

	For the Three Months Ended March 31,	
	2019	2018
Revenues:		
Product sales	$ 7,022	$ 4,071
Costs and expenses:		
Cost of product sales	3,847	1,781
Research and development	7,285	8,199
Selling, general and administrative	7,330	7,592
Loss from operations	(11,440)	(13,501)
Other expense, net	(578)	(353)
Net loss	$ (12,018)	$ (13,854)
Basic and diluted net loss per basic share	$ (0.44)	$ (0.63)
Weighted-average shares used to compute per share calculations	27,567,584	22,025,268

About Aptevo Therapeutics Inc.

Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on developing novel oncology, autoimmune and hematology therapeutics to meaningfully improve patients' lives. Aptevo has a commercial product, IXINITY® coagulation factor IX (recombinant), approved and marketed in the United States for the treatment of Hemophilia B, and a versatile core technology – the ADAPTIR™ modular protein technology platform capable of generating highly-differentiated bispecific antibodies with unique mechanisms of action to treat cancer and autoimmune diseases. Aptevo has a broad pipeline of novel investigational-stage bispecific antibody candidates focused in immuno-oncology and autoimmune disease and inflammation. For more information, please visit www.aptevotherapeutics.com

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including, without limitation, statements regarding potential milestone payments, Aptevo's outlook, financial performance or financial condition, Aptevo's technology and related pipeline, collaboration and partnership opportunities, commercial portfolio, milestones, and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates," "will" and similar expressions are forward-looking statements. These forward-looking statements are based on Aptevo's current intentions, beliefs and expectations regarding future events. Aptevo cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from Aptevo's expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, Aptevo does not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause Aptevo's actual results to differ materially from those indicated by such forward-looking statements, including a deterioration in Aptevo's business or prospects; adverse developments in research and development; adverse developments in the U.S. or global capital markets, credit markets or economies generally; and changes in regulatory, social and political conditions. Additional risks and factors that may affect results are set forth in Aptevo's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K, as filed on March 18, 2019 and its subsequent reports on Form 10-Q and current reports on Form 8-K. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Aptevo's expectations in any forward-looking statement.

Source:
Aptevo Therapeutics
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